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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/627,241	07/24/2003	Richard Strauss	0166/0M993	4177
7278	7590	10/12/2005	EXAMINER	
DARBY & DARBY P.C. P. O. BOX 5257 NEW YORK, NY 10150-5257			YU, GINA C	
			ART UNIT	PAPER NUMBER
			1617	

DATE MAILED: 10/12/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/627,241

Applicant(s)

STRAUSS, RICHARD

Examiner

Gina C. Yu

Art Unit

1617

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 2 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-27 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-27 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____. |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>7/24/2003</u> . | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –
(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

**Claims 1-5 are rejected under 35 U.S.C. 102(b) as being anticipated by
Hayden (US 3249502).**

Claim 1 recites a 2-20 % formaldehyde gel comprising at least one non-active ingredient. The term “for treating a wart” is a preamble which recites the intended future use or purposes of the gel, and is not given patentable weight in this case. See MPEP § 2111.02.

Hayden discloses a 20 % formaldehyde gel by mixing 76 grams of hydroxymethyl cellulose (thickening agent) and 64 ounces of water (1892.48 grams). See Example 1. See instant claims 1, 2, 4, and 5. The reference teaches making a formaldehyde gel wherein the formaldehyde concentration is between 5-60 % by weight or volume. See col. 1, line 51 – col. 2, line 3. See instant claim 3.

**Claims 14-16 are rejected under 35 U.S.C. 102(b) as being anticipated by
Geistlich et al. (GB 905195).**

Geistlich discloses urea-formaldehyde condensation dusting powder “with talc or similar base” wherein the concentration is 5-15 %. See p. 2, lines 8 – 24. See instant claims 14-16.

The term "for treating a wart" is a preamble, which recites the intended future use or purposes of the gel, and is not given patentable weight in this case. See MPEP § 2111.02.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-5, 7, 9-13, 19-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over McKnight et al. (Ulster Med. J., 1968) in view of Ansel (Pharmaceutical Dosage Forms and Drug Delivery System) and Braun et al. (Pharmaceutical Formulation).

McKnight et al. teach treating warts by soaking in 5 % formalin every evening for half an hour and paring down the warts every three days. See p. 40. See instant claims 1-3, 10, 19, and 24.

Ansel teaches that it is a widespread practice in pharmaceutical art to make topically used drugs as gels. See p. 343.

Braun teaches a formulation for a topical clear gel composition and the method of making thereof. See p. 380, Table II. The formulation contains 86.06 % wt purified water, isopropyl alcohol, polysorbate 20, and triethanolamine.

It would have been obvious to one ordinary skill in the art at the time the present invention was made to modify the formaldehyde solution of McKnight et al. by making a

formaldehyde topical gel as motivated by Ansel and Braun because 1) Ansel teaches that topically used drugs are conventionally made into gel and 2) Braun teaches a specific formula for a topical gel composition. The skilled artisan would have had a reasonable expectation of successfully producing a formaldehyde gel for topical use, which would replace the need for soaking the affected skin in formaldehyde solution.

As for claim 22, the Braun reference teaches that silica is useful as rheology modifiers well known in pharmaceutical art, and provides "excellent viscosity and temperature stability". See p. 167-8.

It would have been obvious to the skilled artisan to have further modified the formaldehyde gel of the combined references by further incorporating silica as motivated by Braun because of the expectation of successful producing a topical gel with good viscosity and temperature stability.

With respect to claim 24, lines 7-8, the claim recites, "applying the preparation to the surgical site to remove excessive moisture at the surgical site". While the combined references do not mention applying the formaldehyde solution or a topical gel to absorb moisture, examiner gives no patentable weight to the phrase "to remove excessive moisture at the surgical site" as it is considered a preamble which recites a intended use or purpose of the procedure. See MPEP § 2111.02.

During examination, statements in the preamble reciting the purpose or intended use of the claimed invention must be evaluated to determine whether the recited purpose or intended use results in a structural difference (***or, in the case of process claims, manipulative difference***) between the claimed invention and the prior art. If so, the recitation serves to limit the claim. See, e.g., *In re Otto*, 312 F.2d 937, 938, 136 USPQ 458, 459 (CCPA 1963). (emphasis inserted.)

In this case, regardless of whether the formaldehyde gel is applied "to remove excessive moisture at the surgical site" or to treat wart as taught by McKnight, there is no manipulative difference as to the actual claimed process of treating a skin growth, which requires 1) topically applying 2-20 % of formaldehyde gel to the surgical site, and 2) performing a procedure to remove the affected skin growth. Thus the phrase "to remove excessive moisture at the surgical site" is not considered a claim limitation, and claim 24 is viewed obvious in view of the prior arts as discussed above.

Claims 6 and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Coles et al., Ansel, and Braun et al., and Clark as applied to claims 1-5, 7, 9-13, 19-21, 23-27 as above, and further in view of Flick (Cosmetic and Toiletry Formulations, 2nd ed.).

The gel formulation in the Braun reference contains 0.9 % wt of carbomer (Carbopol ultrez), and 1.50 % wt of triethanolamine. See instant claim 6.

While isopropyl alcohol is present in the amount of 10 % wt, examiner views that the present claim limitation of claim 8 is obvious over the prior art. Generally, differences in concentration will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration is critical. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." See *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). In this case, isopropyl alcohol is a solvent and the needed amount of the solvent would depend on the amount of the solvent, which is in the wide range of 2-20 % by weight, as recited in

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present claim 1. Thus, a skilled artisan would have discovered an optimum weight amount of isopropanol by routine experimentations.

The Braun formula does not include peppermint oil.

Flick teaches a formulation for peppermint foot balm comprising 0.3 % wt of peppermint perfume, Bentone gel, and fungicide. See p. 325.

It would have been obvious to a skilled artisan to modify the formaldehyde gel of the combined references by further incorporating peppermint oil as motivated by Flick because Flick teaches an example of peppermint perfume used in topical composition. The skilled artisan would have had a reasonable expectation of successfully producing a topical formaldehyde gel composition with peppermint scent.

Claim 17 is rejected under 35 U.S.C. 103(a) as being unpatentable over Geistlich et al. (GB 905195) as applied to claims 14-16 as above under § 102 (b), and further in view of Peterson et al (US 5861144).

Geistlich discloses urea-formaldehyde condensation dusting powder "with talc or similar base" wherein the concentration is 5-15 %. See p. 2, lines 8 – 24. See instant claims 14-16. The reference fails to teach silica.

Peterson et al. teach odor absorbing powder composition for topical use, comprising silica, corn starch, and kaolin. See col. 14, Example VI; instant claim 17. The reference teaches that silica is used as moisture absorbers and "slip compounds" to provide enhanced slip/lubrication characteristics of powders and reduced skin-to-skin friction. See col. 4, lines 1 – 29; col. 9, line 55 – col. 10, line 14. The reference also teaches adding antimicrobial agents and antiperspirant agents for added odor control.

See col. 8, lines 33 – co. 9, line 14. The reference teaches using up to 25 %, preferably about 10 % of the antimicrobials. See Id.

It would have been obvious to a skilled artisan to modify the formaldehyde powder of Geistlich et al. by incorporating silica as motivated by Peterson et al. because 1) both references teach antimicrobial powder compositions containing fillers and carriers, 2) Peterson et al. teach using silica as moisture absorber and slip compound to enhance lubrication characteristics of powder composition, and further adding antimicrobial compound preferably about 10 % by the weight. The skilled artisan would have had a reasonable expectation of successfully producing a formaldehyde dusting powder with improved lubrication and moisture absorption.

Claim 18 is rejected under 35 U.S.C. 103(a) as being unpatentable over Geistlich et al. and Peterson et al. as applied to claims 14-17 as above, and further in view of Flick (Cosmetic and Toiletry Formulations, 2nd ed.).

The Example VII in the Peterson reference also contains corn starch, kaolin, and perfume. See also col. 4, line 35 – col. 8, line 11. Corn starch, kaolin, and talc are taught as interchangeable powder carrier. See col. 8, lines 12 – 32.

The combined references fail to teach peppermint oil.

Flick teaches a formulation for peppermint foot balm comprising peppermint perfume, Bentone gel, and fungicide. See p. 325.

It would have been obvious to a skilled artisan to modify the body odor powdery composition of the combined references by further incorporating peppermint oil as motivated by Flick because Peterson et al. teach to incorporate encapsulated or free

perfume to the powder composition and Flick teaches an example of peppermint oil used in topical composition. The skilled artisan would have had a reasonable expectation of successfully producing an antimicrobial powdery composition with peppermint scent.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gina C. Yu whose telephone number is 571-272-8605. The examiner can normally be reached on Monday through Friday, from 8:30 AM until 6:00 PM..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

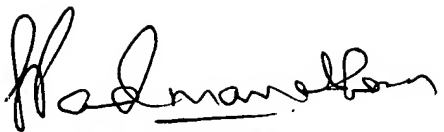
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Gina Yu
Patent Examiner



SREENI PADMANABHAN
SUPERVISORY PATENT EXAMINER